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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,486	09/08/2000	Scott A. Burton	7780.612US01	2827

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER

HAMILTON, LALITA M

ART UNIT	PAPER NUMBER
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3624

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,486

Applicant(s)

BURTON, SCOTT A.

Examiner

Lalita M Hamilton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on amendment filed on November 17, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-16,18-22 and 30-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16,18-22 and 30-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Summary

On August 14, 2003, an Office Action was sent to the Applicant rejecting claims 1-3, 5-11, 15-16, 18-22, and 30-52. On November 17, 2003, the Applicant responded with arguments. In the previous rejection, numbered claims 14 and 53-55 were not included due to an oversight; however, the limitations were included in the rejection. Because of this, the numbered claims are included in this Action, and the Action will be made non-final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-11, 13-16, 18-22, and 30-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (5,733,570) in view of Hoey (4,146,027).

Chen disclose an multi-layer absorbent dressing having a range of absorbencies (**col.1, lines 65-67**) comprising a backing layer (**col.1, lines 60-65**), an absorbent adhesive (**col.1, lines 60-67**), a first absorbent layer containing the reaction product of a hydrophilic, ethylenically unsaturated monomer (**col.5, lines 24-30**) and (**col.1, lines 15-39**) having an absorbency greater than 300% (**col.1, lines 65-68**), an acrylic acid ester of a non-tertiary alcohol having 4 to 14 carbon atoms, a polar, ethylenically

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unsaturated monomer (**col.1, lines 25-40**), the first absorbent layer comprising the reaction product of about 30 to 100 parts by weight of the hydrophilic, ethylenically unsaturated monomer, about 0 to 30 parts by weight of the acrylic acid ester of a non-tertiary alcohol having from 4 to 14 carbon atoms, the second absorbent layer comprising the reaction product of an acrylic acid ester of a non-tertiary alcohol having from 4 to 14 carbon atoms, a hydrophilic, ethylenically unsaturated monomer, a polar, ethylenically unsaturated monomer (**col.1, lines 25-40**), the second absorbent layer comprising the reaction product of about 45 to 80 parts by weight of the acrylic acid ester of a non-tertiary alcohol having from 4 to 14 carbon atoms, about 25 to 40 parts by weight of the hydrophilic, ethylenically unsaturated monomer, about 2 to 20 parts by weight of the polar, ethylenically unsaturated monomer (**col.1, lines 25-40**), the first absorbent layer having an absorbency at least 100 percent greater than the absorbency of the second absorbent layer (**col.1, lines 65-67**), the polar, ethylenically unsaturated monomer comprising partially neutralized acrylic acid (**col.4, lines 4-5**), the dressing being substantially transparent (**col.1, lines 15-20**), a first absorbent layer having an absorbency of at least 200 percent (**col.1, lines 65-67**), wherein the absorbency of the second absorbent layer is at least 50 percent (**col.1, lines 65-67**), the first absorbent layer having an absorbency of at least 400 percent (**col.1, lines 65-67**), the body fluid absorbing material comprising the reaction product of less than about 68 parts by weight of an acrylic acid ester of a non-tertiary alcohol having from 4 to 14 carbon atoms (**col.1, lines 25-40**), greater than about 28 parts by weight of a hydrophilic, ethylenically unsaturated monomer, at least about 4 parts by weight of a partially

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neutralized ethylenically unsaturated carboxylic acid monomer (**col.9, lines 35-40**), the acrylic acid ester comprising a methacrylic acid ester (**col.1, lines 50-53**), and the hydrophilic, ethylenically unsaturated monomer comprising methoxy poly(ethyleneglycol) acrylate (**col.3, lines 52-53**).

Chen discloses that the absorbent dressing may be formed as a multilayer construction (**col.5, lines 25-30**). It is inherent that the absorbent layer may contain less than 10 percent by weight water before application to a patient and that the dressing layer may be cuttable if the user desires. Further, it is inherent that the wound dressing may have a wound facing layer, since the purpose of the dressing is to cover and protect the wound and that the adhesive layer may be apertured to increase absorbency. Chen discloses a range of absorbencies for the absorbent layers; therefore, it is inherent that the second absorbent layer may have an absorbency of less than 50% of the absorbency of the first absorbent layer.

Chen does not disclose a second absorbent non-disintegrating layer in contact with the first absorbent layer, the wound dressing configured to be positioned on a patient such that the second absorbent layer is between the first absorbent layer and the wound, the first absorbent layer being between 10 to 50 mils thick, the second absorbent layer being between 2 to 4 mils thick, the wound-facing film having a void area of between 4 and 10 percent, the apertures having an average diameter less than the combined thickness of the first and second absorbent layers, the first absorbent layer being between 2 to 15 times as thick as the second absorbent layer, or less than 50 percent of the carboxylic acid monomer being neutralized by a base. Hoey teaches

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a wound dressing comprising first and second absorbent layers (**col.1, lines 10-16**), a second absorbent non-disintegrating layer in contact with the first absorbent layer (**col.1, lines 10-16**), the wound dressing configured to be positioned on a patient such that the second absorbent layer is between the first absorbent layer and the wound (**col.1, lines 10-16**), the first absorbent layer being between 10 to 50 mils thick (**col.1, lines 48-50**), the second absorbent layer being between 2 to 4 mils thick (**col.1, lines 35-40**), the wound-facing film having a void area of between 4 and 10 percent, the absorbent layer containing less than 10 percent by weight water before application to a patient (**col.2, lines 15-17**), and the apertures having an average diameter less than the combined thickness of the first and second absorbent layers (**col.1, lines 30-45**). Hoey further teaches the use of minimal amounts of carboxylic acid (**col.4, lines 7-1 and col.4, line 4 to col.5, line 7**) and base for neutralizing, such as ammonium hydroxide (**col.6, lines col.5, line 1 to col.6, line 5**); therefore, it is inherent that less than 50 percent of the carboxylic acid monomer may be neutralized. With regard to the absorbent layers, it is inherent that the first absorbent layer may be between 2 to 15 times as thick as the second absorbent layer, since Hoey teaches that the second absorbent layer may be between 1 to 50 mil. and the first absorbent layer may comprise 1 to 12 layers of absorbent (**col.1, lines 35-40**). With regard to the absorbent layer being substantially insoluble to water, Hoey teaches that the amount of monomer present can contribute to whether or not the polymer is excessively hydrophobic or hydrophilic (**col.5, lines 1-7**); therefore, it is inherent that the absorbent layer may be substantially insoluble to water depending on the amount of monomer present. It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a second absorbent non-disintegrating layer in contact with the first absorbent layer, the wound dressing configured to be positioned on a patient such that the second absorbent layer is between the first absorbent layer and the wound, the first absorbent layer being between 10 to 50 mils thick, the second absorbent layer being between 2 to 4 mils thick, the wound-facing film having a void area of between 4 and 10 percent, the apertures having an average diameter less than the combined thickness of the first and second absorbent layers, the first absorbent layer being between 2 to 15 times as thick as the second absorbent layer, and less than 50 percent of the carboxylic acid monomer being neutralized as taught by Hoey into the dressing disclosed by Chen, so as to gain the maximum benefit of applying a dressing having multiple layers for absorbing exudate from a wound.

Claims 12 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen and Hoey as applied to claim 5 above, and in further view of Dahmen (6,060,557).

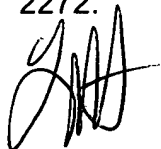
Chen discloses and Hoey teaches the invention substantially as claimed; however, neither reference discloses nor teaches the polar, ethylenically unsaturated monomer comprising N-vinyl acetamide. Dahmen teaches a polymer for absorbing liquids comprising N-vinyl-acetamide (**col.3, lines 25-30**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate N-vinyl-acetamide as an alternative polar, ethylenically unsaturated monomer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

The fax phone number for the organization where this application or proceeding is assigned is (703) 746-6101.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2272.



LMH



VINCENT MILLIN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600